

Appl. No. 10/714,155  
Response to Office Action dated January 25, 2005  
Docket No. TRNSV-029C2

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1. (Currently Amended) A catheter device that is useable to penetrate from the lumen of a blood vessel within a patient's body in which the catheter device is positioned to a target location within the patient's body, said catheter device comprising:

    a catheter having a proximal end and a distal end, said catheter being advanceable into said first blood vessel;

    a tissue penetrator that is advanceable from the catheter, said tissue penetrator being operative to penetrate from the lumen of the blood vessel to target location;

    an imaging transducer ~~fixedly mounted to~~ that provides an imaging signal from which an image of the target location and other anatomical structures located adjacent the first blood vessel can be obtained;

a marker that is useable in cooperation with ~~said imaging transducer and~~ ~~said marker being useable in cooperation with~~ ~~each other to enable the operator to~~ ~~rotationally orient the catheter until the penetrator path indicator is aimed at the~~ ~~second blood vessel, thereby indicating such that~~ ~~that when the tissue penetrator is~~ ~~subsequently advanced from the catheter it will extend from the lumen of the blood~~ ~~vessel to the target location into the lumen of the second blood vessel as desired.~~

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2. (Original) The catheter device of Claim 1 wherein the imaging transducer is an ultrasound imaging transducer.

3. (Original) The catheter device of Claim 2 wherein the ultrasound imaging transducer is selected from the group consisting of:

- an annular phased array
- a rotatable transducer

4. (Original) The catheter device of Claim 3 wherein the phased array transducer is operative to image 360 degrees about the first blood vessel.

5. (Currently Amended) The catheter device of Claim 1 wherein the imageable marker includes comprises a cage on the catheter, said cage comprises comprising a plurality of longitudinal members disposed at circumferentially spaced apart locations about a hollow interior space, a first one of said longitudinal members being located at a circumferential position that is axially aligned with the path that will be followed by the tissue penetrator as it is advanced from the catheter.

6. (Original) The catheter device of Claim 1 wherein the tissue penetrator includes a needle member formed of resilient material that is biased to a preformed curved configuration, said needle member being initially disposed in a retracted position within the catheter and subsequently advanceable from the catheter to an extended position wherein the needle member assumes its preformed curved configuration.

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7. (Original) A catheter device that is useable to facilitate penetration from the lumen of a blood vessel within a patient's body in which the catheter device is positioned to a target location within the patient's body, said catheter device comprising:

a flexible catheter having a proximal end and a distal end, said catheter being transluminally advanceable into said blood vessel;

a tissue penetrator that is advanceable from the catheter to penetrate from the lumen of a blood vessel to a target location, provided that the catheter is rotationally oriented within the blood vessel such that the tissue penetrator is aimed at the target location;

an imaging transducer that comprises a plurality of imaging elements fixedly mounted on the catheter to provide an imaging signal from which an image of the target location and other anatomical structures located adjacent the blood vessel can be obtained; and

said imaging elements being mounted on the catheter at known circumferential locations relative to the path that will be followed by the tissue penetrator as the tissue penetrator exits the catheter, the image obtainable from the imaging signal from said imaging transducer being thereby useable by the operator to rotationally orient the catheter such that, when the tissue penetrator exits the catheter, the tissue penetrator will extend into the target location as desired.

8. (Original) A catheter device as defined in claim 7 wherein the imaging transducer is an ultrasound imaging transducer.

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9. (Original) A catheter device as defined in claim 8 wherein the ultrasound imaging transducer is a phased array transducer.

10. (Original) A catheter device as defined in claim 9 wherein in the phased array transducer is operative to image 360° about the first blood vessel.

11. (Original) A catheter device as defined in claim 7 wherein the catheter device includes an imageable marker on the catheter to form, on the image obtainable from the imaging signal, an indication of the circumferential location of said path.

12. (Original) A catheter device as defined in claim 11 wherein the imageable marker includes an imaging structure formed or mounted on the catheter, said imaging structure comprising a plurality of longitudinal members disposed at circumferentially spaced apart locations about a hollow interior space, a first one of said longitudinal members being located at a circumferential position that is aligned with the path that will be followed by the tissue penetrator as it is advanced from the catheter.

13. (Original) A catheter comprising:

a catheter body having a proximal end, a distal end and a peripheral wall;

said catheter body being receivable within a blood vessel of a human patient;

said catheter body having a penetrator lumen that terminates distally at an exit location on the peripheral wall of the catheter;

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a penetrator operatively engaged to exit from the penetrator lumen, out of the exit location, and away from the catheter body on a predetermined penetrator path; and

a phased array transducer fixedly mounted to the catheter body, said phased array transducer comprising a plurality of transducer elements positioned at circumferentially spaced apart locations, and in known circumferential location relative to said exit port to provide an imaging signal from which an image of the target location and other anatomical structures located adjacent the blood vessel can be obtained to enable the operator to rotationally orient the catheter until the target location is aligned with the location of the exit port such that when the tissue penetrator exits from the catheter it will extend into the target location as desired.

14. (Original) A catheter as defined as in claim 13 including an imageable marker which includes a plurality of circumferentially spaced imageable members which can be sensed by the phased array transducer, said the imageable members being carried by the catheter body in a known circumferential orientation relative to the exit location so that they can be used to locate the target location and in identifying the angular orientation of the exit location.

15. (Original) A catheter as defined in claim 13 wherein the phased array transducer comprises a plurality of imaging elements arranged on the catheter body with at least one of said elements being at a known circumferential location relative to said exit location whereby said at least one element is useable to identify the angular orientation of the exit location.

16. (Original) A catheter as defined in claim 13 wherein the catheter body is sized to be receivable in an artery of a human patient.

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17. (Original) A catheter comprising:

an elongated catheter body having a proximal end, a distal end, a guidewire lumen opening at the distal end of the catheter body and a peripheral wall, at least a distal region of said catheter body being flexible;

said catheter body being receivable within a first blood vessel of a human patient;

said catheter body having a penetrator lumen terminating distally at an exit location on the peripheral wall and a penetrator disposed within said lumen and advanceable out of said exit location;

said catheter body including a major section which includes the proximal end and said exit location and a distal tip section extending from the major section to the distal end of the catheter body;

said distal portion of the distal tip section being of smaller cross sectional area than the adjacent region of the major section; and

an active imaging apparatus carried by the catheter body and including imaging elements the distal tip section and a lead extending proximally from said imaging elements.

18. (Original) A catheter as defined in claim 17 wherein the major section terminates distally in a distal opening and a proximal portion of the distal tip section is received in said distal opening and a distal portion of the distal tip section extends distally of said distal opening.

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19. (Original) A catheter as defined in claim 18 including an imageable marker on said distal portion of the distal tip section.

20. (Original) A percutaneous, transluminal method for creating a flow channel between a first blood vessel that has a wall and a lumen and a second blood vessel that has a wall and a lumen, said method comprising the steps of:

A. providing a catheter device that comprises:

i. a catheter having a proximal end and a distal end, said catheter being advanceable into the lumen of the first blood vessel;

ii. a tissue penetrator that is advanceable from the catheter, said tissue penetrator being operative to penetrate from the lumen of a first blood vessel, through the walls of the first and second blood vessels and into the lumen of a second blood vessel when the catheter is positioned and rotationally oriented within the first blood vessel such that the tissue penetrator is aimed at the second blood vessel;

iii. an imaging transducer fixedly mounted on the catheter to provide an imaging signal from which an image of the second blood vessel and other anatomical structures located adjacent the first blood vessel can be obtained; and,

iv. an imageable marker on the catheter to provide, on the image obtainable from the imaging signal from the imaging transducer, a penetrator path indication indicative of the path that will be followed by the tissue penetrator when the tissue penetrator is advanced from the catheter;

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B. percutaneously inserting and transluminally advancing the catheter into the first blood vessel;

C. actuating the imaging transducer and moving the catheter within the first blood vessel until the penetrator path indication is aimed at the lumen of the second blood vessel; and,

D. advancing the tissue penetrator from the catheter, through the walls of the first and second blood vessels and into the lumen of the second blood vessel.

21. (Original) The method of Claim 20 wherein the tissue penetrator is an elongate member that has a lumen extending longitudinally therethrough and wherein said method further comprises the step of:

E. advancing a first crossing guidewire through the lumen of the tissue penetrator and into the lumen of the second blood vessel.

22. (Original) The method of Claim 21 wherein the method further comprises:

F. retracting the tissue penetrator into the catheter leaving the first crossing guidewire in place such that it extends from the lumen of the first blood vessel into the lumen of the second blood vessel.

23. (Original) The method of Claim 22 wherein the catheter device provided in Step A has a main guidewire lumen that extends longitudinally through at least a portion of the catheter and wherein the method further comprises the steps of:

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I. moving the first crossing guidewire from the lumen of the tissue penetrator, and reintroducing a crossing guidewire into the main guidewire lumen of the catheter; and,

H. readvancing the catheter over the first crossing guidewire to a position wherein the catheter extends through the lumen of the first blood vessel, through the openings created in the walls of the first and second blood vessels by advancement of the tissue penetrator in Step D, and into the lumen of the second blood vessel.

24. (Original) The method of Claim 23 wherein the method further comprises the steps of:

I. actuating the imaging transducer and moving the catheter within the second blood vessel as required to cause the penetrator path indication to be aligned with the lumen of the first blood vessel; and

J. advancing the tissue penetrator from the catheter, through the walls of the first and second blood vessels and into the lumen of the first blood vessel.

25. (Original) The method of Claim 24 further comprising the step of:

K. advancing a second crossing guidewire through the lumen of the tissue penetrator and into the lumen of the first blood vessel.

26. (Original) The method of Claim 25 wherein the method further comprises:

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L. retracts the tissue penetrator into the catheter leaving the second crossing guidewire in place such that it extends from the lumen of the first blood vessel into the lumen of the second blood vessel and back into the lumen of the first blood vessel.

27. (Original) The method of Claim 26 wherein the method further comprises the steps of:

M. providing a connector delivery catheter accompanying a radially expandable connector;

N. advancing the connector delivery catheter over the second crossing guidewire and implanting the radially expandable connector such that the connector extends from the lumen of the first blood vessel, through the openings created in the walls of the first and second blood vessels in Step D, through the lumen of the second blood vessel, through the openings created in the walls of the first and second blood vessels in Step J and back into the lumen of the first blood vessel.

28. (Original) The method of Claim 24 wherein the method is carried out to bypass an obstruction in the first blood vessel and wherein the openings created in the walls of the first and second blood vessels in Step D are proximal to the obstruction and the openings created in the walls of the first and second blood vessels in Step J are distal to the obstruction.

29. (Original) A catheter device according to claim 13 wherein the phased array imaging transducer comprises an annular array of transducer elements, at least one of said transducer elements being a penetrator path indicator element that is in

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known spacial relationship to the path that will be followed by the tissue penetrator as the tissue penetrator is advanced from the catheter.

30. (Original) The catheter device of Claim 29 further in combination with an image display screen for displaying an image received from the phased array transducer.

31. (Original) The catheter device of Claim 29 wherein indicia are provided on the image display screen to distinguish between the portion of the image being received from the penetrator path indicator transducer element and those portions of the image received from the other transducer elements.

32. (Original) The catheter device of Claim 31 wherein said indicia are selected from the group of indicia consisting of:

a series of hash marks that indicate the circumferential location of the image received from said penetrator path indicating element; and,

a line that indicates the circumferential location of the image received from said penetrator path indicating element.

33. (Original) The catheter device of Claim 31 wherein the portion of the image received from the penetrator path indicating transducer element is electronically modified to be visually discernible from the remainder of the image received from the other transducer elements.

34. (Original) A catheter device that is useable to direct an operative device, substance or flow of energy from the lumen of a luminal vessel within a patient's body to a target location within the patient's body, said catheter device comprising:

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a catheter having a proximal end, a distal end and a peripheral wall, said catheter being advanceable into the lumen of said vessel;

an exit location from which an operative device, substance or flow of energy may be directed from the catheter;

an imaging transducer fixedly mounted in a known circumferential location relative to either i) said exit location or ii) a known path that will be followed by the operative device, substance or flow of energy as it is directed from the catheter, said transducer providing an imaging signal from which an image of the target location and other anatomical structures located adjacent the blood vessel can be obtained to enable the operator to rotationally orient the catheter until the target location is aligned with either i) said exit location or ii) the known path that will be followed by the operative device, substance or flow of energy as it is directed from the catheter, such that the operative device, substance or flow of energy will pass into the target location.

35. (Cancelled)

36. (Currently Amended) The catheter device of Claim 35 34 wherein the imaging transducer is an ultrasound imaging transducer.

37. (Original) The catheter device of Claim 36 wherein the ultrasound imaging transducer is an annular phased array of transducer elements.

38. (Original) The catheter device of Claim 37 wherein the phased array transducer is operative to image 360 degrees about the blood vessel.

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39. (Currently Amended) The catheter device of Claim 35 34 wherein a tissue penetrator is advanceable from said exit location.

40. (Currently Amended) The catheter device of Claim 39 wherein said tissue penetrator is comprises a needle.

41. (Original) The catheter device of Claim 40 wherein said tissue penetrator needle has a lumen extending longitudinally therethrough.

42. (Currently Amended) The catheter device of Claim 40 wherein said tissue penetrator is comprises an electrode.

43. (Currently Amended) The catheter device of Claim 40 wherein said tissue penetrator is comprises a flow of energy.

44. (Currently Amended) The catheter device of Claim 35 34 wherein said known circumferential location relative to either i) said exit location or  
ii) a known path that will be followed by the operative device, substance or flow of energy as it is directed from the catheter is displayed on an image display by enhancing the imaging signal received from the imaging transducer correlating to that circumferential location.

45. (Currently Amended) The catheter device of Claim 35 34 wherein said known circumferential location relative to either i) said exit location or ii) a known path that will be followed by the operative device, substance or flow of energy as it is directed from the catheter is displayed by at least one line that is enhancing the imaging signal received from the imaging transducer correlating to that circumferential location.

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46. (Original) A catheter device that is useable to penetrate from the lumen of a patient's blood vessel in which the catheter device is positioned to a target location within the patient's body, said catheter device comprising:

a catheter that has a proximal end and a distal end, said catheter being advanceable into said first blood vessel;

a tissue penetrator that is advanceable from the catheter, said tissue penetrator being operative to penetrate from the lumen of the blood vessel to target location provided that the catheter is rotationally oriented within the first blood vessel such that the tissue penetrator is aimed at the target location;

a catheter braid being incorporated in at least a portion of said catheter body, said catheter braid having a braid angle and a pick count, the braid angle of said catheter braid being such that the pick count is less than 100 picks per inch to thereby minimize the longitudinal elongation of the catheter that may occur as the catheter is warmed from room temperature to body temperature.

47. (Original) The catheter device of Claim 45 wherein the braid angle is such that the pick count is 20-30 picks per inch.

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